The National Blood Policy; A Study in the Politics of Health Paul J Schmidt, M.D.

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The Blood Scene in the 1960s and early 1970s:

- ARC = 40+% of national supply
- AABB + CCBC/ABC = 35%, with some paid donors
- Commercial banks and hospitals = 15%
- Federal Trade Commission; state blood shield laws
- Federal licensing by NIH, Division of Biologics Standards, not by FDA

Hepatitis:

Open Heart Surgery 1960's.
20 units commercial blood/case

• 1965-68 NIH Clinical Center:
Incidence after commercial blood:

51%

• 1968-70 NIH Clinical Center:
Incidence after HbsAg pos blood:

69%

• 1970-72 NIH Clinical Center:
Incidence after voluntary & HbsAg neg:

7%

Background forces 1971:

- AFL-CIO + Red Cross Action Plan
- Titmus: The Gift Relationship; from Human Blood to Social Policy
- NBC Chronolog: Red Cross blood poured down the drain in LA
- Veysey: HR 11828-The National Blood Bank Act and 40 more.
- White House initiatives to replace Apollo space program
- HSMHA+NHLI initiatives for blood demonstration

1972 response by NIH to political pressures from DHEW and Congress:

- Dec 16, 1971 meeting in NIH Director's Office, to plan to retain NIH authority over biologics and save its Division Biologics Standards.
- Task Force (1 NIH, 2 DBS, 2 interns) formed to write a National Blood POLICY, not a National Blood PROGRAM.
- January Task Force produces first document calling for pluralistic policy based on <u>Supply</u>, <u>Quality</u>, <u>Cost and Efficiency</u>. Prepares option papers for President Nixon.

1972 Executive actions

March 9:

Nixon Health Message: Blood a "unique national resource".

• May 2:

Secy Richarson cuts of NIH regulatory authority over blood and biologics and gives the authority to FDA to appease Sen Ribicoff.

NIH Director Marston resigns over political interference:
 NHLBI, NCI

1973 July 10: Secy Weinberger: the government policy has the four original ideas:

SUPPLY

QUALITY

ACCESSIBILITY

EFFICIENCY

Sept 24 Secy's Conference, Helen Nelson, Consumer Federation of America, says that blood is one of the easiest health care problems to solve; If the private sector does not fix it, we will get legislation that will fix it.

Asst.Secy for Health Edwards says executive branch will fix it.

Richard Palmer, AMA President-elect, says AMA will fix it.

NATIONAL BLOOD POLICY Fed Regist 39 (176) 9326-9330, 1974

It is the policy of the federal government to:

10. Implement the Property Legislation of the private sector fails

1974

DHEW publishes implementation plan for comment in Federal Register as cobbled together by AMA for an American Blood Commission [ABC].

Final plan published on September 10 accepts ABC as responsible for the National Blood Policy in a federal "partnership with the private sector".

ABC

"to assure an adequate supply and efficient distribution of safe, high-quality blood...... from voluntary donors"

A private organization of (40) organizations.

'bring consumer groups together with blood collection agencies'

Task Forces commonality, blood data and regionalization were funded by NHBI but donor recruitment was not.

ABC 1974-1988

TASK FORCE

on regionalization foil at the tensumer response

Usual infighting between ARC and AABB on replacement fees continues outside of ABC; lawsuits by commercial blood banks to dissolve ABC.

1977 - FDA requires labeling paid or voluntary, implemented by states

ABC by 1989

An expensive place for blood collectors to <u>talk</u> to consumer groups.

Consumer groups: two kidney, two hemophilia, Cooley's Anemia AABB, ARC and CCBC left.

Without funding, ABC became inactive in 1992.

National Blood POLICY worked, American Blood Commission failed.

POLICY worked because it did <u>NOT</u> operate a National Blood PROGRAM

Goals of POLICY carried out locally in pluralistic society.

Commission failed; patient advocate organizations singleissue.

National Blood POLICY worked, American Blood Commission failed.

Cost issues never resolved. Got worse with zero tolerance for risks

U.S. blood system survived AIDS because of state "blood shield" laws.

Voluntary blood donation succeeds when encouraged, consider income tax credit.

Blood product/service can be regulated/ Utilization practice cannot.